

AAiPS

Newsletter

Vol. 28 Issue 1

January- March 2018



AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244
Colonia, NJ 07067

INSIDE THIS ISSUE

- *President's Message*
- *First Regional Meeting on April 12, 2018*
- *Pharmaceutical News from India*
- *Classified Column*
- *Sponsors*

Newsletter Committee: *Raghu Kasu, Mike Yelvigi and Charchil Vejani*

PRESIDENT'S MESSAGE

Dear Members,

I would like to express my profound gratitude to the entire AAiPS membership for giving me the opportunity to serve our organization. We have worked diligently and together as a formidable team under the leadership of Rina Choksi. I am sure we will continue to work with the same enthusiasm this year. The regular meetings with the Executive Committee and the chairs of various committees, apart from being an excellent forum for exchange of ideas, have reflected this zeal and commitment. AAiPS has also drawn up a road map for the next five years. The action plan includes recommendations of the three committee's - *Vision Committee, Awards Committee and Finance Committee formed by the Executive committee.*

On the collaborative side, we have initiated a dialogue to work together with NJPhAST and INTERPHEX. AAiPS Executive Committee has agreed to have a joint regional meeting on April 12, 2018 in the New Jersey area.

We shall continue to work hard on all fronts-bringing in new members and renewing the annual members and finding a way to serve our life members. I am very grateful to both new and old sponsors for their support. Finally, I would thank the members of the hardworking and dedicated executive and working committees for their continued support. The executive committee is looking for additional volunteers to help in several of AAiPS committees.

I encourage all members to take an active role by attending our networking regional and annual meetings, recruiting new members, organizing local chapters. Please feel free to contact me with ideas on how to make AAiPS a stronger organization.

Regards
Vijai Kumar
President

QUOTE OF THE QUARTER

“Coming together is a beginning, Keeping together is progress. Working together is success.”
- Henry Ford

REGIONAL MEETING UPDATE**NEW JERSEY- APRIL 12, 2018**

The first regional meeting will be held jointly with NJPhAST on April 12, 2018 at the Hanover Marriott Hotel in Whippany, NJ.

Pharmaceutical Control Strategy – what does it mean and how do we apply? By Martin Warman.

In pharmaceutical manufacturing there is often confusion over the term control strategy. The view from an automation engineering perspective is often totally different than the view from a product quality/release view point, and often documents meant primarily to help the end user have to include definitions of the terms (for example ICH Q8 (R2)). Even within a specific usage of the term there is multiple perspectives, which can lead to further confusion and the need for clarification.

The purpose of this presentation is to give an overview of the world of control strategy, try to illustrate where some of the opposing viewpoints come from but also to do a deeper dive into the most common implementations of pharmaceutical control strategy, using the FDA complexity pyramid to help explain not only what pharmaceutical Control Strategy means, but more so how it can be differently applied (both even batch and continuous manufacturing) and also, to try and take a look into the future and suggest how pharmaceutical control will be impacted/changed by activities such as advanced manufacturing/Industry4.0.

Please register Online at www.aaips.org, by mail or on-site. For more information visit www.aaips.org

Biography Martin Warman

Martin is Director of Martin Warman Consultancy Ltd, providing services to support PAT enabled Control Strategies for both batch and continuous manufacturing (CM).

Previously he spent 7 years as a Scientific Fellow II at Vertex Pharmaceuticals

supporting the use of PAT within a QbD framework, from process development to enabling Control Strategies for real time release. This includes a special focus on CM and process innovation, and he was one of the co-leads of the Vertex Scale-up and Process Innovation Team (SUPIT) responsible for developing the Vertex DLR platform on which the first approved CM process runs.

He has over 25 years' experience in the field having worked in the pharmaceutical (incl. 14 years leading the Global PAT Development Team Pfizer, GMS), the instrument sector (with Dionex), in petrochemical (Shell) and in academia (University of Westminster).

Martin is also on the Executive Committee of ASTM E55 covering Pharmaceutical Manufacturing and chairs the E55.01 sub-committee covering PAT and Risk Management. He also and sits on the ISPE PAT & LCS Community of Practice (CoP) global steering committee, and chairs the UK Affiliate PAT & LCS CoP steering committee.



**MARK YOUR CALENDARS FOR
NEXT REGIONAL MEETING ON
MAY 10, 2018**

Venue:

Crown of India Restaurant.

Address: 660 Plainsboro Rd,
Plainsboro Township, NJ 08536

Speaker:

Lakshmi Raghavan, Ph.D.
Founder & President, Solaris Pharma

Topic:

*Design Considerations in Development of
Generic Dermatologicals*

Time;

Social hour 5:30 - 6:15PM

Presentation by Guest speaker 6:15 – 700 PM

Dinner 7:00 – 8: 30 PM

**AAiPS Networking Event at
INTERPHEX
April 17-19, 2018**

Javits Center, New York City, New York

Pharmaceutical News:**Ex-Merck chemist faces prison for allegedly
dumping cyanide**

A former senior analytical chemist at Merck is facing criminal charges in Pennsylvania for allegedly stealing potassium cyanide from a lab and pouring it into a storm drain after finding out about an investigation.

According to the police, Richard O'Rourke stole 220 grams of the dangerous chemical in December to use as a rodent poison. Another senior colleague at Merck noticed O'Rourke take the chemical, pour it into a beaker, and then into a Nalgene water bottle, the police said.

Merck alerted authorities, and O'Rourke heard about it, police said. Fearing he'd be found out, O'Rourke dumped the cyanide into a storm drain, potentially endangering the water supply.

He faces charges of causing or risking catastrophe, theft, receiving stolen property and recklessly endangering another person. Causing or risking catastrophe is a felony that can carry up to a 20-year prison term.

Merck first contacted the Pennsylvania Department of Environmental Protection, who "immediately attempted to locate the dump site of the potassium cyanide and began monitoring the water supply for signs of the chemical and toxicity," authorities said.

Officials tested water systems for two weeks before determining that a hard rainfall sufficiently flushed the system, according to a press release.

Source: Fierce Pharma News.

**INDIAN PHARMACEUTICAL
ASSOCIATION (IPA) UPDATES**

Newly elected IPA office bearers

President: Dr. Rao V.S. Vadlamudi

Hon.General Secretary: Mr.Kaushik Desai

Hon.Tresurer: Dr. Hemant Mondkar

Editor-Pharma Times: Dr.Alka Mune

Editor-IJPS: Dr.Divakar Goli

PHARMA NEWS FROM INDIA**New Drug Controller General of India Appointed**

Joint Drugs Controller Dr S Eswara Reddy has been appointed as the new Drugs Controller General of India (DCGI).

He started his career as a Drugs Inspector in CDSCO, West Zone, Mumbai in 1998 and has good experience in GMP, GCP and GLP audits He got Best Drugs Inspector award in 2005, He was promoted as Assistant Drugs Controller of India in 2009

Dr Reddy actively participated in formulating Drugs and Cosmetics Amendment Bill 2013, involved in strengthening Indian drug regulatory system during 12th Five Year Plan, streamlined medical devices division and handled international matters such as MoU, SOI and quality issues.

Latest US FDA 483 observations at Aurobindo's Hyderabad unit

While there have been many episodes in the past where inspectors have found batch records in the waste area or deleted electronic files of valid testing results, one begins to wonder if the recent FDA Form 483 observations at Aurobindo Pharma's Unit IV

facility in Hyderabad would qualify as a classical breakdown of data-integrity.

During an inspection performed between February 12, 2018 and February 20, 2018, investigators found that the firm failed to log analytical reference standards that were received in the laboratory one month before the inspection into the laboratory inventory management system (LIMS). The firm also did not store them as recommended on the Certificate of Analysis (CoA).

These observations indicate there is product-related data without the necessary traceability which was not contemporaneously recorded. Looking at the MHRA's view, the absence of these facets would affect data integrity.

On its part, Aurobindo clearly mentioned in its filing with the bourses that "none of the observations are related to data integrity"

Concerns at Biocon's Malaysia and Sun's Halol facilities

The FDA also shared their recent observations by posting the Form 483s issued to the sterile manufacturing operations of two other major Indian manufacturers — Sun Pharma and Biocon.

Biocon's plant in Malaysia had the FDA investigator raise concerns over media fill practices — a recurring concern in most sterile drug manufacturing facilities.

The FDA also highlighted the deficiencies found in Biocon's investigations as deviations. It specified in the Form 483 that Biocon's "quality unit initiated more than 1,040 deviations from 2015 to 2018, but has failed to extend the investigations of deviations (DR) and OOS discrepancies to other batches and products that were manufactured under similar conditions."

The latest FDA inspection at Sun's Halol facility, which received a warning letter over two years ago, had three observations related to the firm's operations.

During the inspection at Sun, the Grade A area was found to have rough, cracked and uneven surfaces which were difficult to clean. Moreover, the

investigators observed extensive use of sealant around all the HEPA filter units.

There was also no scientific justification for omitting this specific sampling location.

Source: Excerpted from The Pharma Compass Newsletter –

Pharmaceutical Manufacturing & R &D facility available in Pearl River, NY.

The site, of which Pfizer still occupies a portion, is one of their five primary research sites and a central hub for vaccine and BioTherapeutics research and development.

The campus will remain the home for Pfizer's biotechnology research group and is also the home of Sanofi Protein Sciences, Profectus Biosciences, Urban Electric Power and Anellotech.

We are able to offer over 1,500,000 sf of the following types of buildings and amenities:

- GMP Consumer Packaging
- GMP Warehouse
- GMP Laboratory space
- GMP Formulation and Manufacturing
- R & D
- Vivarium
- Office
- 20 megawatt cogeneration plant-able to offer below market utility rates
- Redundant & dual fed power systems

We are part of the New York Life Science initiative as well as Start Up NY which provides economic incentives for qualified new businesses.

We are able to accommodate all pharmaceutical sizes and needs from startups to existing companies.

Contact Information:

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Or
Mike Yelvigi: 908-625-9512

Obituary

Dr. Michael Pikal

We regret to inform you of the sad demise of a distinguished scientist Dr. Michael Pikal. He was a Pfizer Distinguished Endowed Chair in Pharmaceutical Technology

Professor of Pharmaceutics

Department of Pharmaceutical Sciences

University of Connecticut, School of Pharmacy.

- B.A. St. John's University, Minnesota, Ph.D. Iowa State University
- Research Interests
- Lyophilization of proteins and other pharmaceuticals – process, formulation and stability.
- Solid state chemistry of proteins
- Dynamics in the glassy state and pharmaceutical stability

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PEOPLE ON THE MOVE

This column is provided for information about our members' professional progress and changes. If you have any information to publish, please contact Dr Charchil Vejani at vejani@gmail.com

ADVERTISEMENT RATES

The rates of advertisement for the AAiPS newsletter are as follows:

One year (four issues): \$1000 full page, \$500 half a page, \$250 quarter page

One time (one issue): \$400 full page, \$200 half a page, \$100 quarter page.

Contact: Mukund Yelvigi, myelvigi@hotmail.com

No advertisements under a quarter page

AAiPS THANKS ITS SPONSORS

AAiPS thanks the following sponsors for their continued support of this organization.

Platinum Sponsors: ACG North America, Capsugel-Lonza

Gold Sponsors: Globe Pharma, Federal Equipment, FMC, Colorcon, Halo Pharma

Silver Sponsors: Glatt, DFE Pharma

AAiPS Office Bearers for 2018-2019

President: *Vijai Kumar*

Vice President: *Samit Deb.*

Secretary: *Shrikant Bhonsle.*

Treasurer: *Suggy Chrai*

Immediate Past President: *Rina Choksi*

Members-at-large:

Dr. Sampat Singhvi,

Mukund "Mike" Yelvigi,

Dr. Uday Doshi

Program Committee: *Dr. Rupa Doshi*

Sponsorship: *Mr. Jaydeep Vaghashiya*

Student Awards and Scholarship:

Dr. Hardeep Saluja

Communication: *Dr. Charchil Vejani*

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